

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EISAI CO., LTD., et al.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

Civil Action No. 05-5727 (GEB)

OPINION AND ORDER

I. INTRODUCTION

Pending before this Court is a discovery dispute raised by Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries, Ltd., and Gate Pharmaceuticals (“Teva” or “Defendants”) in an informal joint submission dated September 8, 2009, requesting that Plaintiffs Eisai Co., Ltd. and Eisai Inc. (“Eisai” or “Plaintiffs”) respond to two Document Requests, one Interrogatory and one 30(b)(6) deposition topic¹ all seeking information related to Defendants’ allegations of inequitable conduct. This matter presents the Court with a dispute regarding the outer limits of relevant discovery to prove an inequitable conduct theory in a patent infringement litigation.

Having considered the parties’ submission, the Court now sets forth its opinion on each of those issues. For the following reasons, the relief sought is **DENIED**.

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

On December 7, 2007, Plaintiffs initiated this action alleging infringement of U.S. Patent No. 4,895,841 (“the ‘841 patent”). (Docket Entry # 1, the “Complaint”). The ‘841 patent, which

¹ Teva initially sought to compel testimony regarding a second 30(b)(6) deposition topic, Topic Number 3, but has since withdrawn this request. (Joint Submission Table at 3).

was issued on January 23, 1990 and arose from the prosecution of U.S. Patent Application No. 07/209,339 (“the ‘339 application”), claims “donepezil hydrochloride,” the active ingredient in Aricept, a market-leading drug in the treatment of Alzheimer’s Disease. (See Complaint at ¶13).

At the inception of this case, Defendants filed an Answer in which they asserted the affirmative defense of obviousness. On May 15, 2007, Defendants moved to amend their Answer to add the affirmative defense of inequitable conduct stemming from Plaintiffs’ alleged failure to disclose the following co-pending patent applications to the patent examiner in charge of the ‘339 application:

- 1) Applications 06/946,459 and 07/321,624 (“the ‘459 application family”) which issued as U.S. Patent Nos. 4,849,431 (“the ‘431 patent”) and 4,942,169 (“the ‘169 patent”);
- 2) Applications 07/016,035 and 07/408,106 (“the ‘035 application family”), which issued as U.S. Patent Nos. 4,876,262 (“the ‘262 patent”) and 4,996,215 (“the ‘215 patent”);
- 3) Application 07/177,662 (“the ‘662 application”) which issued as U.S. Patent No. 4,921,863 (“the ‘863 patent”); and
- 4) Application 07/273,971 and its continuation applications, U.S. Patent Application Nos. 07/495,112, 07/668,327, and 07/825,423 (“the ‘971 application family”) which issued as U.S. Patent No. 5,196,439 (“the ‘439 patent”).

On December 6, 2007, this Court granted Teva’s motion to amend its answer to add inequitable conduct claims with regard to Eisai’s alleged failure to disclose the co-pending ‘459 application family (culminating in the ‘431 patent) and the existence of a 1984 article in the *Journal of Medicinal Chemistry* authored by Richard A. Kenley (the “Kenley Reference”) to the United States Patent and Trademark Office (the “PTO”). (Docket Entry # 102, the “December 6th Order”).

The Court denied the motion with regard to the other three co-pending applications. (*Id.*). The parties did not appeal the December 6th Order and Teva subsequently filed a Corrected Amended Answer adding the inequitable conduct defense solely with regard to the ‘459 application family and

withdrawing its affirmative defense of obviousness. (Docket Entry # 105). Notably, the Corrected Amended Answer also included references to the co-pending applications which this Court held could not be included. The references were included to demonstrate an alleged “pattern of non-disclosure” which Teva alleges is relevant to Eisai’s alleged intent to deceive. (*Id.* at ¶ 41).

In response to the Corrected Amended Answer and pursuant to Fed. R. Civ. P. 12(f), Eisai moved to strike the references to the co-pending applications other than the ‘459 application family. On February 11, 2008, this Court granted Plaintiffs’ motion to strike, finding that Teva’s Amended Answer, with respect to the references to the co-pending applications other than the ‘459 application family, remained legally insufficient. (Docket Entry #133 at 6, the “February 11th Order”).

Teva then appealed this Court’s February 11th Order and on July 6, 2009, Judge Ackerman found that Teva’s Corrected Amended Answer should not be struck and Teva “should be permitted, within the limits of the law, to develop its case for intent to deceive.” (Docket Entry # 264, the “July Order” at 28). Judge Ackerman further noted that “[t]he parties should focus at all times on the only asserted basis of inequitable conduct here - the failure to disclose the ‘459 application - and the relevance of the other co-pending applications to intent to deceive with regard to this sole basis of inequitable conduct.” (*Id.*).

In the meantime, in May 2008, this Court heard oral argument on a joint submission dated January 31, 2008 raising similar discovery issues to those raised in the instant dispute. The Court ruled from the bench denying Teva’s motion to compel discovery with respect to the co-pending applications without prejudice and the abandoned applications with prejudice. Teva also appealed the Court’s May 2008 ruling in conjunction with its appeal of the February 11th Order. In the July Order, Judge Ackerman vacated this Court’s denial of Teva’s motion to compel discovery with

respect to the co-pending and abandoned applications. Judge Ackerman found that while Teva's discovery requests with regard to the abandoned applications "appears speculative," the Court would "vacate the decision on the issue to allow for full reconsideration at this stage and in light of this Opinion" and expressed "no view on the permissibility or scope of discovery regarding the two issues implicated in Teva's appeal of the May Bench Order." (July Order at 29).

III. DISCUSSION

A. Legal Standard

It is axiomatic that the scope of discovery under the federal rules is broad. *See Kresefsky v. Panasonic Commc'ns & Sys. Co.*, 169 F.R.D. 54, 64 (D.N.J. 1996). Fed. R. Civ. P. 26(b)(1) permits the parties to "obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party..." Relevancy is defined as "any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case..." Fed. R. Civ. P. 26(b); *see also Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351, 98 S.Ct. 2380, 2389 (1978); *Lugosch v. Congel*, 218 F.R.D. 41, 44 (N.D.N.Y. 2003) ("[t]o be relevant, the request for information must be 'germane' to the subject matter of the claim, defenses or counterclaims, though not necessarily limited by such pleadings, and is not controlled by whether it will be admissible at trial"). Here, the Court must consider whether the discovery sought is relevant to Teva's inequitable conduct allegations.

While the scope of discovery is broad, a district court has wide discretion in managing the discovery phase of a case. *See Cooper Hospital/Univ. Med. Ctr. v. Sullivan*, 183 F.R.D. 119, 127 (D.N.J. 1998); *Kresefsky*, 169 F.R.D. at 64. This is especially true where the Magistrate Judge has managed the case from the outset and "developed a thorough knowledge of the proceedings." *Pub.*

Interest Research Group v. Hercules, Inc., 830 F.Supp. 1525, 1547 (D.N.J. 1993), *aff'd* on other grounds and *rev'd* on other grounds, 50 F.3d 1239 (3d Cir. 1995).

Furthermore, Fed. R. Civ. P. 26(b)(2)©, which governs the scope of discovery, permits the court to limit discovery if the request is “unreasonable cumulative or duplicative” or “the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties’ resources, the importance of the issues at stake in the action, and the importance of the discovery in resolving the issues.” Fed. R. Civ. P. 26(b)(2)(C)(I, iii); *see also Bayer A.G. v. Betachem, Inc.*, 173 F.3d 188 (3d Cir. 1999) (“although the scope of discovery ... is unquestionably broad, this right is not unlimited and may be circumscribed”); *Gutierrez v. Johnson & Johnson, Inc.*, 2002 U.S. Dist. LEXIS 15418, *10 (D.N.J. 2002) (“discovery is not permitted where the discovery sought is irrelevant to the claims at issue, where the requests were tendered in bad faith, or where the requests are unduly burdensome”). Even if the Court finds the subject matter of the discovery requests are relevant to the inequitable conduct defense, the Court must then consider the burden on Eisai to comply as compared with the benefit to Teva.

Based on the July Order, Teva now seeks to once again compel discovery to bolster the inequitable conduct allegations in two categories relating to the co-pending and abandoned applications. The Court will address each category and the corresponding discovery requests below.

B. Category One: Co-pending Applications

In this category, Teva seeks to compel the production of documents responsive to Teva’s Document Request Number 82 propounded in Defendants’ Sixth Set of Requests for Production of Documents dated December 21, 2007. Specifically, Teva seeks “[a]ll documents concerning consideration or discussion by anyone in Eisai’s patent department during the period from March

1984 to January 1990 pertaining to the disclosure to the United States PTO of the co-pendency of any U.S. patent application with claims encompassing benzylpiperidine derivative compounds at anytime during its prosecution in connection with any other pending U.S. patent application claiming benzylpiperidine derivative compounds.” (Joint Submission Appendix, Ex. 3).

Since the initial request and in connection with this joint submission, Teva has essentially narrowed the request seeking Eisai “to produce all documents concerning any consideration or discussion pertaining to the disclosure to the United States PTO of the co-pendency of any other U.S. patent application having claims encompassing benzylpiperidine derivative compounds during the prosecution of the seven other issued U.S. patents² which Teva has previously identified having at least one claim that includes benzylpiperidine derivative compounds.” (Joint Submission Table at 2). Teva argues that (1) the search would not be burdensome for Eisai and (2) any responsive documents are relevant to assess “whether the withholding of the ‘459 application at issue here was done with similar deceptive intent.” (*Id.* at 1).

In response, Eisai has objected to this document request on the grounds that it is “overbroad, burdensome, irrelevant and speculative to the extent that the discovery does not relate to the prosecution of the ‘841 patent application or the copending applications cited in Teva’s amended answer as they may relate to the ‘841 patent application.” (Joint Submission Table at 2). Eisai asserted that the four co-pending applications in the amended answer do not correspond to the seven listed patents and thus, even the narrowed request exceeds the scope of the amended answer. (*Id.*). Eisai argued that permitting Teva to engage in discovery directed to the co-pending applications

² The patents are U.S Patent Nos. 4,849,431 (‘431 Patent), 4,876,262 (‘262 Patent), 4,921,863 (‘863 Patent), 4,942,169 (‘169 Patent), 4,977,165 (‘165 Patent), 4,996,215 (‘215 Patent), and 5,100,901 (‘901 Patent). (Joint Submission Table at 2).

would in essence lead to “collateral litigation” warned against by Judge Ackerman. (*Id.*). As such, Eisai asserted that it searched for documents reflecting consideration of the copending applications noted in the Corrected Amended Answer in connection with the prosecution of the ‘841 patent and found no responsive documents. (*Id.* at 1).

Having considered the parties’ arguments, the Court finds that Document Request Number 82 (even as narrowed) is overbroad and exceeds the scope of allowable discovery. The prosecution of the seven patents noted by Teva do not pertain to the prosecution of the patent at issue in this case. Teva has failed to advance any compelling reason how these seven patents, a few of which were only brought to this Court’s attention in the joint submission, are within the proper scope of discovery. Moreover, during argument, Teva’s counsel framed the issue as follows:

So, we believe we’re entitled to discovery. Why they acknowledge the duty in the ‘468 application, but breached it in the application leading to the patent in suit and all other documents regarding the consideration or the discussion in the other prosecutions within this limited subset of those applications containing or encompassing claims that have a benzylpiperidine group.

(Transcript of Oral Argument at 11:1 to 11:9). Teva’s request as framed by counsel demonstrates how far outside of the Corrected Amended Answer Teva has strayed. Documents and consideration of disclosure of documents related to the prosecution of the patent at issue are relevant, but straying to the prosecution history of other patents that Teva now claims contain a benzylpiperidine group is outside the scope of relevant discovery in this matter.

Nonetheless, Eisai has represented that it has searched for and found no documents reflecting consideration or discussion of the co-pending applications in the Corrected Amended Answer in connection with the prosecution of the application for the ‘841 patent. (Joint Submission Table at

1). Cognizant of the District Court's warning to avoid "succumbing to the unwelcome distraction of an extended fishing expedition resulting in a virtual side-trial on prior co-pending applications relevant only to intent" (July Order at 28), this Court finds that any discovery outside of that which Eisai has already searched would prove to only be a distraction and likely will not lead to the discovery of any relevant information to Teva's inequitable conduct defense. As such, not only is the request overbroad, but Eisai's search has rendered any additional narrowing of the request moot. The burden to Eisai to perform a subsequent search would far outweigh any potential benefit to Teva. Therefore, Teva's motion with regard to Category One is denied.

C. Category Two - Abandoned Applications

In the second category, Teva seeks to compel discovery of Eisai's abandoned applications directed to benzylpiperidine derivative compounds. Specifically, Teva moves to compel answers to Interrogatory 17, documents in response to Document Request 79 and testimony in response to 30(b)(6) Topic Number 4.

Interrogatory Number 17 propounded in Defendants' Fifth Set of Interrogatories dated December 21, 2007 asks Eisai to "[i]dentify by application number each patent application claiming benzylpiperidine derivative compounds or the use thereof, including, but not limited to, the use of administration of such compounds for treating dementias, assigned to Eisai that was filed from March 1984 to January 1009 that were subsequently abandoned." (Joint Submission Appendix, Ex. 5). Should Eisai identify any abandoned applications, Document Request Number 79 propounded in Defendants' Sixth Set of Requests for Production of Documents seeks "all documents concerning each U.S. patent application identified in response to Interrogatory No. 17..." (Joint Submission Appendix, Ex. 3). Finally, 30(b)(6) Topic Number 4 propounded in the Notice of Rule 30(b)(6)

Deposition of Plaintiffs dated January 4, 2008 seeks testimony reflecting “any consideration or discussion during the period from March 1984 to January 1990 pertaining to the possible disclosure to the United States PTO of the co-pendency of any U.S. patent application having claims encompassing benzyloperidine derivative compounds, which application was subsequently abandoned, during the prosecution of U.S. Patent Application No. 07/209,339.” (Joint Submission Appendix, Ex. 4).

As all three are related, Teva advanced substantially the same arguments in support of the three discovery requests. First, Teva asserted that it can only obtain this discovery from Eisai because the information sought is uniquely in Eisai’s possession. (Joint Submission Table at 5). Second, Teva argued that the information sought is relevant to demonstrate a pattern of intent motivating Eisai’s alleged non-disclosure of the ‘459 application. (*Id.*). Finally, Teva argued that conducting the search would not be burdensome because Eisai has already conducted a similar search. (*Id.* at 7).

Eisai objected to the discovery demands calling them a “speculative fishing expedition” and asserting that even if there were responsive documents, they would be irrelevant and the burden to find them would be enormous. (Joint Submission Table at 5). Nonetheless, Eisai asserted that it searched for and found no abandoned Eisai U.S. patent applications filed between March 1984 and January 1990 which are not referenced in an issued U.S. patent and have claims referring to benzyloperidine “as a chemical constituent of the molecule.” (*Id.*). Therefore, Eisai claimed that all three discovery requests are moot. (*Id.* at 8).

Teva objected to the parameters of Eisai’s search on the grounds that the search was too narrow and not exhaustive. Teva demanded that Eisai search for abandoned applications “claiming

benzylpiperidine derivative compounds of the use thereof.” (Joint Submission Table at 6).

At argument, Teva spent a significant amount of time attempting to demonstrate the difference between searching for claims referring to benzylpiperidine “as a chemical constituent of the molecule” (as Eisai did) and abandoned applications “claiming benzylpiperidine derivative compounds of the use thereof” (as Teva would prefer). Based on Teva’s explanation, this Court is not convinced that there is any significant difference between the parameters of Eisai’s search and the search sought by Teva. (*See* Transcript of Oral Argument at 16:14 to 18:3, 21:13 to 21:16, 25:5 to 28:15, 29:21 to 30:3). Therefore, based on Eisai’s representation to this Court about the result of the searches it conducted, it appears that Eisai has already expended a significant effort in its previous search and found no abandoned applications.

Any expanded search sought by Teva is vague, overbroad and unduely burdensome. To conduct such a broad search, Eisai would have to again review over 140 boxes, dating back more than twenty years that are located in a storage unit, to search for a reference, the parameters of which Teva could not adequately articulate at argument. (*See* Plaintiff Eisai’s Opposition to Teva’s Renewed Motion To Compel at 11). Although this Court doubts the relevancy of the discovery requests seeking information about the so-called abandoned applications, it does not reach a conclusion on that subject. Instead, given Teva’s inability to articulate a distinction between the search conducted by Eisai and Teva’s request, the Court finds that any further search by Eisai would be a burden that outweighs the benefits to Teva. Eisai has represented that it has not found any relevant responsive abandoned applications. Further searching would only succeed in delaying this already protracted case as Eisai has stated it would take approximately three more months to conduct any subsequent searches given Teva’s vague parameters. (Transcript of Oral Argument 33:22 to 23).

Even if Eisai were to conduct such a search, it is highly unlikely any relevant documents would be identified.

As such, Teva's motion to compel discovery in category two is denied.

SO ORDERED.

/s/ Esther Salas

Esther Salas

UNITED STATES MAGISTRATE JUDGE